

CLAIMS

1. Method of monitoring the operationality of a member for cutting off the flow of a fluid through an extracorporeal circuit (2),
the said circuit (2) having at least one length of deformable tubing (10) on which there is active at least one flow cut-off member (9) having at least one movable portion (11) that can be actuated between an open condition, in which it allows the fluid to pass through, and at least one closed condition, in which it prevents the fluid passing through the said length of tube (10),
the said method comprising the following phases:
 - moving the movable portion (11) of the cut-off member (9) from the said open condition towards the said closed condition;
 - associating at least one dynamic parameter with a motion of the said movable part (11);
 - determining a value of the said at least one dynamic parameter relating to the said movable part (11) at least during the said movement;
 - checking that the value assumed by the said dynamic parameter satisfies a predetermined criterion of acceptability.
2. Method according to Claim 1, characterized in that the phase of moving the movable portion (11) of the cut-off member (9) involves progressively compressing the said length of tube (10).
3. Method according to Claim 1, characterized in that the value of the said dynamic parameter is determined in relation to at least one first position assumed by the movable part (11), the said first portion being intermediate between a rest position, assumed by the movable part (11) in the open condition of the cut-off member (9), and a working position, assumed by the movable part

(11) in the closed condition of the cut-off member.

4. Method according to Claim 1, characterized in that
5 the said at least one dynamic parameter is designed to describe a condition of motion of the said movable portion (11) and is selected from the following dynamic parameters:
 - 10 - p1, corresponding to a time interval dT taken by the movable part (11) to move between the first predetermined position and a second predetermined position at a distance from the said first position,
 - 15 - p2, corresponding to a speed of the said movable part (11) at the said first position,
 - p3, corresponding to an acceleration of the said movable part (11) at the said first position,
 - p4, corresponding to a function $F(p1)$ of the said parameter p1,
 - 20 - p5, corresponding to a function $F(p2)$ of the said parameter p2,
 - p6, corresponding to a function $F(p3)$ of the said parameter p3, and
 - 25 - p7, corresponding to a function of two or more of the said parameters p1, p2, p3.
5. Method according to Claim 4, characterized in that
30 the said parameter p corresponds to the time dT taken by the said movable part (11) to move from the first predetermined position to the second position, the second position being subsequent to and at a distance from the first.
6. Method according to Claim 1, characterized in that
35 a plurality of phases are carried out to determine the values V_i assumed by the said dynamic parameter at successive predetermined positions assumed by the movable part (11) during the said movement.

7. Method according to Claim 5, characterized in that the said parameter is the time taken by the movable part (11) to move from the first position, corresponding to the valve-open condition, to a second position, corresponding to or close to a valve-closed condition.
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8. Method according to Claim 1, characterized in that if the said value of the parameter p does not satisfy the said criterion of acceptability, a correction phase is then carried out.
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9. Method according to Claim 1, characterized in that if a said value of the parameter p does not satisfy the said criterion of acceptability, an alarm phase is then carried out.
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10. Method according to Claim 8, characterized in that the correction phase comprises a subphase of intervening on the movement of the movable part (11) of the said flow cut-off member (9).
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11. Method according to Claim 6, characterized in that the values V_i assumed by the said parameter p are compared with corresponding criteria of acceptability and, if a predetermined number of the said values do not satisfy their particular criteria of acceptability, an alarm phase is carried out.
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12. Method according to Claim 6, characterized in that the values V_i assumed by the said parameter p are compared with their respective ranges of acceptability and, if a predetermined number of the said values are not within their respective ranges of acceptability, a correction phase is carried out.
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13. Method according to Claim 12, characterized in that the correction phase comprises a subphase of intervening on the movement of the movable part (11) of the said flow cut-off member (9).
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14. Method according to Claim 1, characterized in that the said criterion of acceptability is either predetermined or is calculated as a function of one or more of the following parameters:
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- p_i , corresponding to or proportional to the pressure in the vicinity of the length of tube when the cut-off member is in the open condition;
 - f_l , corresponding to the rate of flow of fluid

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 - through the length of tube when the cut-off member is in the open condition.
15. System for arresting the flow through an extracorporeal fluid circuit (2) comprising:
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- at least one flow cut-off member (9) active on a length of deformable tubing (10) forming part of the said circuit, this cut-off member having at least one movable portion (11) that can be actuated between an open condition, in which it

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 - allows the fluid to pass through, and at least one closed condition, in which it prevents the fluid passing through the said length of tube ;
 - an actuator (14) connected to the said cut-off member (9) for moving at least the said movable

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 - portion (11); and
 - a monitoring unit (15) active on the said actuator (14) and capable of:
 - a) causing a movement of the movable portion (11) of the cut-off member (9) towards the

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 - said closed condition;
 - b) determining a value of at least one dynamic parameter associated with a motion of the said movable part (11) during the said movement;

c) checking that the value assumed by the said dynamic parameter satisfies a criterion of acceptability.

5 16. System according to Claim 15, characterized in
that the cut-off member (9) comprises a fixed
portion (12) defining, in conjunction with the
said movable portion, a housing seat for the said
length of tubing (10), the movable portion (11)
10 being designed, in its movement towards the closed
condition, to approach the fixed portion so as
progressively to compress the said length of
tubing (10).

15 17. System according to Claim 15, characterized in
that the said dynamic parameter is determined in
relation to a first position of the movable part,
intermediate between a rest position, assumed by
the movable part in the open condition of the cut-
20 off member (9), and a working position, assumed by
the movable part in the closed condition of the
cut-off member (9).

25 18. Device according to Claim 17, characterized in
that the said at least one dynamic parameter is
designed to provide information about a condition
of motion of the said movable portion (11) and is
selected from the following dynamic parameters:

- 30 a) p1, corresponding to a time interval dT taken
by the movable part (11) to move between the
first predetermined position and a second
predetermined position at a distance from the
said first position,
b) p2, corresponding to a speed of the said
35 movable part (11) at the said first position,
c) p3, corresponding to an acceleration of the
said movable part (11) at the said first
position,

- d) p4, corresponding to a function $F(p1)$ of the said parameter p1,
 - e) p5, corresponding to a function $F(p2)$ of the said parameter p2,
 - 5 f) p6, corresponding to a function $F(p3)$ of the said parameter p3, and
 - g) p7, corresponding to a function of two or more of the said parameters p1, p2, p3.
- 10 19. System according to Claim 18, characterized in that the said monitoring unit (15) is designed to calculate the value of the said parameter p as the time interval dT taken by the said movable part
- 15 (11) to move from the first predetermined position to the second position, the second position being subsequent to and at a distance from the first.
- 20 20. System according to Claim 15, characterized in that the said monitoring unit (15) is designed to carry out a plurality of phases to determine the values V_i assumed by the said dynamic parameter at successive predetermined positions assumed by the movable part (11) during the said movement.
- 25 21. System according to Claim 19, characterized in that the said monitoring unit (15) is designed to determine the value of the said parameter as the time interval dT taken by the movable part (11) to move from the rest position, corresponding to the
- 30 open condition of the cut-off member, to the first position (20).
- 35 22. System according to Claim 15, characterized in that the monitoring unit (15) is capable of activating a subsequent correction and/or alarm phase if the said value of the parameter p does not satisfy the criterion of acceptability.

23. System according to Claim 15, characterized in that the said criterion of acceptability is predetermined.
- 5 24. System according to Claim 15, characterized in that the said monitoring unit (15) is capable of calculating the criterion of acceptability as a function of:
- 10 - p_i, corresponding to or proportional to the pressure in the vicinity of the length of tube when the cut-off member is in the open condition;
 - f_l, corresponding to the rate of flow of fluid through the length of tube when the cut-off member is in the open condition.
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25. System according to Claim 20, characterized in that the said monitoring unit (15) is designed to activate a correction phase and/or an alarm phase if a predetermined number of the said values V_i are not within their respective ranges of acceptability.
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26. System according to Claim 22 or Claim 24, characterized in that during the correction phase the monitoring unit (15) is designed to intervene on the said actuator (14) to vary at least the speed of movement of the movable part (11) of the said cut-off member (9).
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27. System according to Claim 17 or according to Claim 20, characterized in that the said monitoring unit (15) comprises:
- 30 a) a control unit (16), and
 - 35 b) means (17) for detecting one or more placings of the said movable portion (11) in successive positions, sending corresponding signals to the control unit (16), the said control unit being capable of determining the value of the said

dynamic parameter or parameters following receipt of the said signal or signals.

- 5 28. System according to Claim 27, characterized in that the said detector means (17) comprise position sensors (20, 21) connected to the said control unit (16).
- 10 29. System according to Claim 27, characterized in that the control unit (16) comprises at least one microprocessor block (18), or CPU, and a memory (19) connected to the CPU.
- 15 30. System according to Claim 15, characterized in that the monitoring unit (15) is designed to execute the said phases in response to an automatic preprogrammed command.
- 20 31. System according to Claim 22 or 25, characterized in that the monitoring unit (15) is designed to execute the said phases in response to the detection of a situation of danger.
- 25 32. Blood treatment appliance comprising:
a) an extracorporeal circuit equipped with at least one blood treatment unit having at least one first (4a) and one second (4b) chambers, separated from each other by a semipermeable membrane (7); at least one collecting line (5)
30 for collecting blood from a patient connected to an inlet of the said first chamber (4a); at least one second line (6) for returning the blood to the patient, in fluid communication with an outlet of the said chamber; and
35 b) means (27) for setting up a flow of fluid through the said extracorporeal circuit, characterized in that it comprises a system (8) according to any one of the preceding Claims 15 to 31.

33. Appliance according to Claim 32, characterized in that it comprises sensor means (25) for detecting predetermined parameters for monitoring correct operation of the said appliance (1), the said sensors (25) being designed to send corresponding signals to the monitoring unit (15) for determination of potential conditions of danger.
34. Appliance according to Claim 32, characterized in that the said sensor means (25) comprise an air bubble detector (26) connected to the extracorporeal circuit (2).
35. Appliance according to Claim 33, characterized in that, upon determination of the said situations of danger, the monitoring unit is capable of sending commands for closure of the cut-off member and for carrying out the phases of the monitoring method as claimed in one of Claims 1 to 14.
36. Unit for monitoring the operationality of a member for cutting off the flow of a fluid in an extracorporeal circuit, characterized in that it is capable of carrying out the phases of the monitoring method according to one of Claims 1 to 14.
37. Software program comprising instructions for making a monitoring unit (15) with a microprocessor unit (18) capable of carrying out the phases of the monitoring method according to one of Claims 1 to 14.
38. Program according to Claim 37, characterized in that it is stored on a magnetic and/or optical recording medium.

39. Program according to Claim 37, characterized in that it is stored in a computer memory (19).
- 5 40. Program according to Claim 39, characterized in that it is carried by an electrical or electromagnetic carrier.
41. Program according to Claim 37, characterized in that it is stored in a read-only memory.